

**CRITERIA FOR PRIOR AUTHORIZATION**

Orilissa™ (elagolix)

**PROVIDER GROUP:** Pharmacy**MANUAL GUIDELINES:** All dosage forms of the following medications will require prior authorization.  
Elagolix (Orilissa™)**CRITERIA FOR INITIAL APPROVAL:** (must meet all of the following)

- Patient has a diagnosis of endometriosis causing moderate to severe pain
- Patient must be 18 years of age or older
- Prescriber must attest that all medication-specific safety criteria, as defined in table 1, is met
- The prescribed dose does not exceed 200 mg twice daily

**LENGTH OF APPROVAL:** 6 months**CRITERIA FOR RENEWAL:**

- Patient must not have coexisting moderate or severe hepatic impairment
- Patient must not have been receiving 200 mg twice daily
- The patient has not been previously treated with Orilissa for a total duration greater than or equal to 24 months
- Prescriber must attest that the patient has received clinical benefit from continuous treatment with the requested medication.
- Prescriber must attest that all medication-specific safety criteria, as defined in table 1, is met.

**LENGTH OF APPROVAL:** 6 months**TABLE 1. MEDICATION-SPECIFIC CRITERIA**

MEDICATION-SPECIFIC CRITERIA
<ul style="list-style-type: none"><li>• Patient must not have severe hepatic impairment (Child-Pugh class C)</li><li>• Patient must not be pregnant during treatment</li><li>• Patient must have bone mineral density evaluated and must not have a known diagnosis of osteoporosis</li><li>• Patient must not be receiving strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (cyclosporin, eltrombopag, gemfibrozil, rifampin)</li><li>• Patients with no or mild hepatic impairment may receive 150 mg daily not to exceed 24 months duration or 200 mg twice daily, not to exceed 6 months duration</li><li>• Patients with moderate hepatic impairment (Child-Pugh Class B) may only receive 150 mg daily, not to exceed 6 months duration</li></ul>

APPROVED PA Criteria

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE